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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,106	07/03/2001	Xiaochuan Zhou	4222-4002US1	9228
21586	7590	03/29/2004	EXAMINER	
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760			HANDY, DWAYNE K	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,106

Applicant(s)

ZHOU ET AL.

Examiner

Dwayne K Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30,34,35,38-49,100-109,145-150 and 159-162 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30,34,35,38-49,100-109,145-150 and 159-162 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 6-8, 15, 17, 21, 22, 24-26, 34, 40, 47-49, 100, 102-106, 109, 145-147, 150, 159, 160, and 162 are rejected under 35 U.S.C. 102(b) as being anticipated by Zanzucchi et al. (5,643,738). Zanzucchi et al. teach a method of synthesizing a plurality of compounds in parallel on a partitioned substrate. The embodiment of the device that is most relevant to the instant claims is shown in Figures 1A-6A. The device is comprised of a disk containing a number of modules comprised of chambers (50, 34, 36, 40, 42, 44) connected by a channel (38). The number of modules formed on the disk may be 267, 534, or up to 1500 for parallel processing of samples (column 6, lines 35-45). Materials of construction are disclosed in column 6, lines 13-23 and include silicon wafers and glass. Figure 5B shows a cover plate (63) made of glass. The Examiner considers this feature as meeting the limitation of a "window plate". While describing an example of using the device in Example 1, Zanzucchi discloses the

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attachment of DNA probes in a well (column 10, lines 38-43). The use of an electro-optic light source for illuminating chambers and detection elements for analyzing the material contained therein is shown in Figure 6A and described in column 10, lines 5-28.

3. Claims 1-4, 6-9, 15, 17-19, 34, 35, 38-40, 47, 48, 145-150, and 159-162 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfost et al. (6,485,690). Pfost et al. teach a system for processing multiple fluid samples. The device is comprised of a number of stacked plates which contain wells and/or other fluid processing elements such as fluid distribution chambers, valves, and pumping mechanisms. The embodiments of the device most relevant to the instant claims are shown in Figures 1-8. The basic embodiment shown in Figure 2 includes a top plate (12) with an array of chambers (20) connected by channels (22) in the middle plate (14) to the wells (30) of the bottom plate (16). Each chamber (20) of the top plate is formed over (overlap) a well (30) on the bottom plate to form a flow through device. The number of chambers/wells in the plate may range from 96 to 1536 (column 9, lines 5-14). Pfost recites materials of construction in column 6, lines 33-41 and includes silicon, polymers, plastics, and glass. The Examiner believes the use of glass would meet the limitation of a "window plate". Pfost discloses tapered channels in column 18, lines 38-41. The use of flow restrictions in both inlet and outlet channels is shown in Figures 6-8. The outlets of the wells (20) from the upper plate (12) are narrower than the well itself and the inlets (32) to the wells (30) of the lower plate are narrower than the wells. Optical detection

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elements are shown in Figure 32. General detection elements are described in column 11, lines 40-55. Finally, in column 7, lines 29-46, dimensions for channels and wells are given and include ranges which meet the ratio limitations of claim 35.

4. Claims 1, 7-9, 17, 20-24, 26-28, 34, 40-42, 47, 150, 159, 160, and 162 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheppard, Jr. et al. (6,143,247). Sheppard et al. teach a device and method for performing affinity-based assays on a platform. The platform contains a number of chambers with affinity particles that are connected by microchannels. A basic embodiment of the system is shown in Figure 5 and includes the platform, a light source, focusing lens, filters, a dichroic mirror, lens, and detector. Materials for the platform are disclosed in column 15, line 55 through col. 16, line 9 and include silicon, glass, plastics and polymers. In column 16, lines 10-42 Sheppard discloses the use of particles which are immobilized on surfaces of the platform through covalent links in both two and three-dimensional patterns. These particles include proteins and short chain peptides as well as antibodies, ligands, and other cell fragments (col. 18, lines 35-42). Sheppard shows the chambers connected by microchannels in Figures 3C-4H and includes branched channels for distributing fluids to different chambers from a common line. Bead and resin use is disclosed in column 26, lines 20-25.

Inventorship

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfoest et al. (6,485,690) in view of Demers et al (5,840,256). Pfoest teaches every element of claims 5 and 10-14 except for 10,000 reaction cells and the claimed distance

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between the cells. Demers teaches a plate for a reaction system comprised of a cell array of up to 100,000 cells. As shown in the Table of Figure 1 and described in column 6, the plate comes in several formats including 1000, 4000 and 10,000. In order to accommodate such a large number of cells micron scale spacing is used between the cells (column 6, lines 10-63). It would have been obvious to one of ordinary skill in the art to combine the array size and spacing of Demers with the device of Pfost. One would use the dimensions from Demers to put as many reaction cells as possible on the device. This would allow for the processing of a greater number of compounds.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (5,643,738) in view of Stabile et al. (5,872,623). Zanzucchi teaches every element of claim 16 except for a masking element. Stabile teaches a parallel detection system that uses optical detection to analyze the content of wells. The optical system is best shown in Figure 3A and includes a window array. The window array has transparent windows which may be closed at a given moment so that only a given subset of cells is illuminated at a given moment. It would have been obvious to one of ordinary skill in the art to combine the window array of Stabile with the device of Zanzucchi. One would add the window array of Stabile in order to obtain the benefits of isolating certain cells from illumination as taught by Stabile.

9. Claims 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (5,643,738) in view of Sheppard, Jr. et al. (6,143,247). Zanzucchi teaches every element of claims 107 and 108 except for the immobilization of molecules

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on multiple surfaces and in three-dimensions. Sheppard teaches an affinity binding based system for detecting particles/compounds. In their system Sheppard et al. teach the use of covalently bound binding reagents to bind analytes of interest in channels or chambers so they can be analyzed. The covalently bound reagents may comprise a three-dimensional structure to bind particulates. It would have been obvious to one of ordinary skill in the art to combine the immobilization teachings of Sheppard with the device of Zanzucchi. One would immobilize affinity/binding molecules in more than one dimension to provide the greatest amount of surface area possible to bind analytes of interest.

10. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfof et al. (6,485,690) in view of Stabile et al. (5,872,623). Pfof teaches every element of claims 43-45 except for a masking element. Stabile teaches a parallel detection system that uses optical detection to analyze the content of wells. The optical system is best shown in Figure 3A and includes a window array. The window array has transparent windows which may be closed at a given moment so that only a given subset of cells is illuminated at a given moment. It would have been obvious to one of ordinary skill in the art to combine the window array of Stabile with the device of Pfof. One would add the window array of Stabile in order to obtain the benefits of isolating certain cells from illumination as taught by Stabile.

11. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfof et al. (6,485,690) and Stabile et al. (5,872,623) and further in view of Sheppard, Jr.

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(6,143,247). Pfost and Stabile, as combined above, teach every element of claim 46 except for the use of linker molecules to immobilize molecules. Sheppard teaches an affinity binding based system for detecting particles/compounds. In their system Sheppard et al. teach the use of covalently bound binding reagents to bind analytes of interest in channels or chambers so they can be analyzed. It would have been obvious to one of ordinary skill in the art to combine the teachings of Sheppard with the device of Pfost. One would use covalent links to chemically secure compounds to prevent the affinity compounds from being washed away during the mechanical stress of processing.

12. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al. (6,143,247) in view of Zanzucchi (6,118,126). Sheppard, Jr. teaches every element of claim 29 except for the use of a porous polymer. As stated above, Sheppard Jr. teaches an affinity-based system for detecting particulates in a fluid. In column 22, Sheppard discloses that using fluorescence is a preferred way of detecting the analytes. Zanzucchi teaches a method for enhancing fluorescence when detecting compounds. The method includes the use of a polymer membrane such as nylon or polycarbonate because it provides a textured surface which provides the enhancement (column 17, lines 47-65). It would have been obvious to combine the polymer membrane from Zanzucchi with the device of Sheppard. One would add the membrane to enhance fluorescence yields as taught by Zanzucchi.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zanzucchi et al. (5,863,708) show another teachings of an earlier cited device. Mian et al. (6,319,469) teach a microfluidic system with multiple channels and chambers for analysis. McNeely et al. (6,296,020 and 6,591,852) teach microfluidic devices that use channel restrictions to control flow in the microchannels. Kopf-Sill et al. (6,358,387) teach a high throughput microfluidic system.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
March 21, 2004


Jill Warden
Supervisory Patent Examiner
Technology Center 1700